

Nestlé Corrections (in blue) on Table from Ross Products Division of Abbott Laboratories' Comment to the Docket dated 2/7/06

Table 1. Factors Affecting Interpretation of Data* Submitted in Support of Nestlé's Proposed Qualified Health Claim (June, 2005)

Study	Not peer reviewed	Not double-blinded	Methods Score ¹	Additional diet intervention ²	Environmental Control/advice	Confirmation of allergic symptoms by controlled challenge ³
Baumgartner (1998) <u>Meta-analysis</u>	X <u>Peer-reviewed</u>	X ⁴	<u>-</u> ^{5,6}	X		No ⁷
Chan (2002)		X <u>Investigators blinded</u>	-	X <u>Exclusive formula 4 mo</u>		No
Chan-Yeung et al (2000); Becker et al (2004)				X <u>BF with maternal restrictions encouraged up to 4mo; no solids until 6 mo; no cow's milk, seafood, peanuts in 1st yr</u>	X	No <u>(But other confirmatory tests were used)</u>
Chandra (1989; 1991; 1997) ⁸			2	X <u>Exclusive formula 6 mo; introduction of solid foods in particular order</u>		No ⁸ <u>Yes, but only mentioned in 1997 publication</u>
De Seta et al (1994)		X <u>Not specified in publication</u>	0	X <u>Exclusive formula 6 mo</u>		No
Exl et al (1998, 2000)		X	-	X <u>BF encouraged; exclusive formula 4 mo</u>		No
Marini et al (1996)	X <u>Supplement of peer-rev'd publication</u>	X <u>Investigators blinded</u>	2	X <u>BF encouraged; exclusive formula 5 mo</u>	X	No <u>(But other confirmatory tests were used)</u>
Osborn and Sinn (2003) <u>Meta-analysis</u>	X	X ⁴	<u>-</u> ⁶	X		No ⁷

***The Ross table omits many of the studies submitted in support of Nestlé's proposed Qualified Health Claim, all of which were included in Appendices C-II and C-III of the Summary-Scientific Data section of the June, 2005 petition.**

Table 1 (cont'd)

Study	Not peer reviewed	Not double-blinded	Methods Score ¹	Additional diet intervention ²	Environmental Control/advice	Confirmation of allergic symptoms by controlled challenge ³
Schmidt et al (1995)	X	X ⁹	Excluded-no randomization	X		No
Tsai et al (1991)		X <u>Not specified in publication</u>	-	X <u>BF 1-2 mo then exclusive formula 6 mo</u>		No <u>(But other confirmatory tests were used)</u>
Vandenplas et al (1992, 1995)			4	X <u>Exclusive formula 4 mo followed by grated apple</u>		Unknown ¹⁰ <u>Yes, but method not fully described</u>
Von Berg et al (2003)			-	X <u>BF encouraged; no solids until 6 mo</u>		No ¹¹ <u>Yes, in specific cases</u>
Willems et al (1993)		X <u>Not specified in publication</u>	Excluded-included infants without family history	X <u>Exclusive formula 3 mo</u>		No

¹As evaluated and reported by Schoetzau et al (2001) with a range of scores from 0-7 (higher scores better). Randomization, double-blinding, description of dropouts, and description of non-compliance assessed.

²Includes delay of solid food introduction, avoidance of food allergens, recommendations for exclusive breastfeeding, and/or pregnancy/lactation diet restrictions.

³As evaluated and reported by Muraro et al (2004).

⁴Meta-analysis included studies that were not double-blind.

⁵(-) Not evaluated by the authors.

⁶Meta-analysis included studies reviewed and excluded by Schoetzau et al (2001) or with Method Scores <4.

⁷Meta-analysis not evaluated by Muraro et al (2004) but included studies that had not confirmation of allergic symptoms by controlled challenge.

⁸Serious questions regarding the scientific validity of this study have been raised (Canadian Broadcasting Corporation, 2006). No immunologic or food challenge confirmation mentioned until 1997 paper; no explanation for why these important data were not presented with the original results.

⁹Parents selected their infant's feeding group.

¹⁰Method not described (i.e., blinding, placebo).

¹¹Controlled elimination/challenge procedures only performed in cases of suspected food allergy with gastrointestinal manifestations.